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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/854,414

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Gerald Horn

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24573

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EXAMINER

FAY, ZOHREH A

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

01/14/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/854,414	Applicant(s) HORN, GERALD	
	Examiner ZOHREH A. FAY	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,11,13-15,18-28,37-40 and 43-47 is/are pending in the application.
- 4a) Of the above claim(s) 10,11,13-15,18-28,37-40 and 43-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 74-77 are presented for examination.

Claims 10, 11, 13-15, 18-38, 37-40 and 43-65 are withdrawn from consideration.

Claims 12, 29-36, 41-42 and 66-73 are canceled.

Claims 74, 75 and 77 are rejected under 35 U.S.C. 102 (b) as being anticipated by Galin et al. (US 4,443,441) for the reasons set forth on pages 2 of the office action of August 14, 2008.

Claims 74-77 are rejected under 35 U.S.C. 101 for the reasons set forth on pages 3-4 of the office action of August 14, 2008.

Claims 74-77 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Galin et al. (4,443,441) in view of Galin (US 5,612,027) for the reasons set forth on pages 2-3 of the office action of May 11, 2009.

Applicant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Applicant in his remarks argues that Galin et al. reference is directed to six alpha-adrenergic blocking agents, the preferred agent and the only working example is directed to thymoxamine, and thus Galin fails to recognize the improved benefit of the ophthalmic night vision formulation with phentolamine. The arguments are noted. Applicant's attention is directed to claim 1 of Galin reference, which claims phentolamine as one alpha-adrenergic blocking agent for ophthalmic use. Applicant also refers to the data in the specification trying to show the advantages of phentolamine on vision dim in comparison to other alpha-adrenergic blocking formulation. It is the examiner's position that such data are not commensurate in scope with the claimed language. Such data use one concentration of phentolamine and one

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concentration of other alpha-adrenergic blocking agents. Furthermore, the data do not show any correlation between the obtained results and the improvement of vision.

Finally, in the absence of any difference between the claimed composition and the prior art compositions, it is expected that the prior art composition also have the same benefits as the claimed composition. Applicant's remarks regarding the Galin et al. have been noted. Applicant in his remarks argues that the viscous composition of Galin et al. being used for the treatment of anterior chamber of the eye at the concentrations of 10 mg/ml and 30mg/ml is different than the viscoelastic artificial tear of the present invention. It is the examiner's position that the prior art uses the viscoelastic agents within the claimed concentrations in combination with miotic agents. Therefore, such reference makes clear that the use of viscoelastic agents in combination with miotic agents in ophthalmic formulations as old and well known.

Applicant's arguments regarding the double patenting rejection have been noted. Such rejection will be maintained until the filing of a Terminal Disclaimer.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZF

/Zohreh A Fay/

Primary Examiner, Art Unit 1612